

Exhibits 11

CHRONOLOGY OF SIGNIFICANT EVENTS DURING REGULATORY REVIEW PERIOD

Date	Event Description	Reg. Number
4-Feb-1983	IND submitted for Miconazole Nitrate 0.25% Ointment, and assigned IND Number 21,542.	IND 21,542
3-Mar-1983	IND 21,542 placed on clinical hold because of safety concerns.	IND 21,542
21-Sep-1983	IND 21,542 released from clinical hold after JJCC addressed the concerns.	IND 21,542
7-Nov-1983	Study 10833/10842.33 (U.S. Clinical Study in infants) started.	IND 21,542
13-Jan-1984	Second Investigator added.	IND 21,542
23-Jun-1984	Study 10833/10842.33 (U.S. Clinical Study in infants) ended; date for Final Clinical Report June 16, 1998.	IND 21,542
19-Jul-1988	Study 12966.37C (Absorption Study carried out in Mexico) started.	IND 21,542
7-Dec-1988	Study 12966.37B (Phase III Study carried out in Australia) started.	IND 21,542
27-Feb-1989	Study 12966.37A (Phase III Study carried out in Australia) started.	IND 21,542
14-Jun-1989	Study 12966.37C (Absorption Study carried out in Mexico) ended; date for Final Clinical Report March 31, 1998.	IND 21,542
10-Nov-1989	Study 12966.37B (Phase III Study carried out in Australia) ended; date for Final Clinical Report April 8, 1998.	IND 21,542
21-Mar-1990	Study 12966.37A (Phase III Study carried out in Australia) ended; date for Final Clinical Report June 30, 1998.	IND 21,542
19-May-1992	Geriatrics Study by Janssen Pharmaceutica, NV started.	IND 21,542
13-Apr-1993	Geriatrics Study by Janssen Pharmaceutica, NV ended; date for Final Clinical Report April 1996.	IND 21,542
1-Apr-1996	Geriatrics Study by Janssen Pharmaceutica, NV, date for Final Clinical Report.	IND 21,542
6-Sep-1996	Request for Pre-NDA Meeting with Division of Dermatologic and Dental Drug	IND 21,542
18-Dec-1996	Submitted Pre-NDA Meeting Briefing Package.	IND 21,542
9-Jan-1997	Pre-NDA Meeting.	IND 21,542
31-Mar-1998	Study 12966.37C (Absorption Study carried out in Mexico) date for Final Clinical Report.	IND 21,542
8-Apr-1998	Study 12966.37B (Phase III Study carried out in Australia) date for Final Clinical Report.	IND 21,542
22-May-1998	Teleconference with Chemistry group.	IND 21,542
16-Jun-1998	Study 10833/10842.33 (U.S. Clinical Study in infants) date for Final Clinical Report.	IND 21,542
30-Jun-1998	Study 12966.37A (Phase III Study carried out in Australia) date for Final Clinical Report.	IND 21,542
24-Aug-1998	NDA 21-026 submitted by JJCC and received by FDA, for PEDIASSTAT (miconazole nitrate 0.25%) Ointment.	NDA 21-026
6-Oct-1998	Amendment (Chemistry).	NDA 21-026
20-Oct-1998	Teleconference initiated by FDA too discuss fileability and potential review issues.	NDA 21-026
16-Nov-1998	Amendments (response to October 20, 1998 telephone conference).	NDA 21-026
20-Nov-1998	Amendments (response to October 20, 1998 telephone conference).	NDA 21-026
7-Jan-1999	Amendments (response to October 20, 1998 telephone conference).	NDA 21-026
1-Mar-1999	Amendments (response to October 20, 1998 telephone conference).	NDA 21-026
16-Mar-1999	Response to FDA Request for Information.	NDA 21-026
24-Mar-1999	Response to FDA Request for Information.	NDA 21-026
25-Mar-1999	Amendment (Response to FDA Request for Information).	NDA 21-026
30-Mar-1999	Amendment (Response to FDA Request for Information).	NDA 21-026
28-Jun-1999	FDA issued Not-Approvable Letter.	NDA 21-026
1-Jul-1999	JJCC indicates intent to respond to the Not-Approvable Letter.	NDA 21-026
21-Jan-2000	Amendment filed providing a response to the June 28, 1999 Not-Approvable Letter.	NDA 21-026
1-Feb-2000	Amendment.	NDA 21-026
17-Mar-2000	Amendment.	NDA 21-026
28-Mar-2000	Amendment.	NDA 21-026
10-May-2000	Safety Update.	NDA 21-026
22-May-2000	Advisory Committee briefing package submitted.	NDA 21-026

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Date	Event Description	Reg. Number
30-Jun-2000	FDA Advisory Committee Meeting.	NDA 21-026
24-Jul-2000	Second Not-Approvable Letter was issued.	NDA 21-026
31-Jul-2000	Notification that sponsor would fully respond to the July 24, 2000 Action Letter.	NDA 21-026
3-May-2001	Request for formal meeting.	NDA 21-026
20-Jun-2001	Formal meeting to discuss clinical study requirements to gain NDA approval and potential for OTC status.	NDA 21-026
30-Aug-2001	Meeting Minutes from June 20, 2001 FDA meeting.	NDA 21-026
21-Jun-2002	Transfer of IND 21,542 ownership from JJCC to Barrier and acceptance of ownership and responsibility by Barrier.	NDA 21-026
27-Sep-2002	Amendment - Information Package for meeting with FDA scheduled for October 7, 2002.	NDA 21-026
7-Oct-2002	Meeting to discuss proposed plan to address the deficiency outlined in the Not-Approvable Letter; Barrier communicated its intention to market the product as Rx only.	NDA 21-026
13-Nov-2002	Request for Special Protocol Assessment for the required additional study (Protocol No. BT100 USA/001 "A Double Blind, Randomized, Multicenter Study of 0.25% Miconazole Nitrate Ointment in the treatment of Cutaneous Candidiasis Complicating Diaper Dermatitis) was submitted to the Agency.	NDA 21-026
22-Dec-2002	Division provided comments on this protocol.	NDA 21-026
12-Feb-2003	Teleconference held to discuss the comments contained in the Division's correspondence of December 22, 2002.	NDA 21-026
21-Jul-2003	Barrier requested a Type A meeting because there were still outstanding issues regarding the "combination policy".	NDA 21-026
3-Sep-2003	Meeting at which the Agency agreed to have further internal discussions and to convey the results of those discussions to Barrier.	NDA 21-026
18-Dec-2003	Teleconference during which the Agency communicated the outcome of its internal discussions and the issues surrounding the "combination policy" were resolved.	NDA 21-026
27-Jul-2004	Information and Guidance Meeting (type C) in preparation for the submission of NDA Amendment (Complete Response to July 24, 2000 second Not-Approvable Letter).	NDA 21-026
24-Nov-2004	Barrier submitted an amendment to NDA 21-026 containing a complete response to the deficiencies contained in the July 24, 2000 Not-Approvable Letter.	NDA 21-026
5-Jan-2005	Barrier submitted an addendum to the pending amendment to provide Section 3.2.P.2.3.5 "In-Vitro Studies" which was inadvertently omitted from the November 24, 2004 amendment.	NDA 21-026
8-Feb-2005	Information Letter.	NDA 21-026
16-Feb-2005	Barrier response to comments provided by DMETS regarding the Agency rejection of proposed proprietary name; two new names submitted.	NDA 21-026
10-Mar-2005	Barrier partial response to CMC portion of February 8, 2005 Information Letter, providing additional manufacturing and stability information on zinc oxide and petrolatum, and responded to seven other CMC requests.	NDA 21-026
15-Mar-2005	Barrier response to remaining issues (clinical questions, statistical questions and microbiology questions) contained in FDA February 8, 2005 Information Letter.	NDA 21-026
5-Apr-2005	FDA facsimile communication.	NDA 21-026
12-Apr-2005	FDA facsimile communication requesting further chemistry.	NDA 21-026
14-Apr-2005	Barrier submitted Safety Update Report and Medication Guide to NDA 21-026 per FDA request.	NDA 21-026
22-Apr-2005	Barrier response to FDA facsimile communications of April 5, 2005 and April 12, 2005, including names and contract information for the Umicore facility in the Netherlands, Barrier's supplier of Zinc Oxide, and revised S-Sections containing more detailed CMC data for Zinc Oxide and White Petrolatum.	NDA 21-026
29-Apr-2005	Barrier response to five questions raised in FDA facsimile communication of April 12, 2005, requesting additional chemistry, manufacturing, and control information.	NDA 21-026

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6-May-2005	Barrier request for a new Trade Name, Zixida, for the product because DMETS did not recommend use of our first proposed trade name, Zimykan.	NDA 21-026
17-May-2005	Barrier response to FDA e-mail communication containing the Agency's proposed draft labeling.	NDA 21-026
19-May-2005	FDA facsimile communication raising four CMC issues.	NDA 21-026
20-May-2005	Barrier response to four CMC issues raised by FDA facsimile communication of May 19, 2005.	NDA 21-026
24-May-2005	Barrier received a "Not-Approvable" Action Letter from the Dermatology Division.	NDA 21-026
27-May-2005	Barrier notified FDA of intent to file an amendment (complete response) to the May 24, 2005 Action Letter.	NDA 21-026
3-Jun-2005	Request for End-of-Review Meeting.	NDA 21-026
20-Jun-2005	Barrier submitted the Briefing Package for an End-of-Review Meeting with the Division on July 14, 2005, which meeting had been formally requested on June 3, 2005.	NDA 21-026
14-Jul-2005	End-of-Review Meeting; Agency requested a Complete Response to their "Not-Approvable" Action Letter.	NDA 21-026
15-Aug-2005	Barrier Complete Response to Not-Approvable Letter of May 24, 2005.	NDA 21-026
25-Aug-2005	Barrier amends the complete response of August 15, 2005, to provide current proposed labeling, being a resubmission of Barrier's May 17, 2005 draft labeling submission.	NDA 21-026
24-Oct-2005	Barrier provided Revised Draft labeling, replacing the previous Trade Name, Zimykan, with the new proposed Trade Name, VUSION.	NDA 21-026
14-Nov-2005	Barrier submitted electronic version of Revised Draft labeling provided October 24, 2005.	NDA 21-026
26-Jan-2006	Barrier submitted General Correspondence requesting permission to use the first batch of tubes that had already been manufactured with the agreement that all subsequent batches would be printed according to the FDA's requests.	NDA 21-026
30-Jan-2006	Barrier provided revised draft labeling again in response to FDA comments that were received January 25, 2006.	NDA 21-026
3-Feb-2006	FDA facsimile with Phase 4 Commitment Requests.	NDA 21-026
6-Feb-2006	Barrier submitted Final Safety Update Report.	NDA 21-026
7-Feb-2006	Barrier communication agreeing to FDA Phase 4 Commitment Requests of February 3, 2006, with modified dates.	NDA 21-026
8-Feb-2006	Teleconference to negotiate the Agency's Revised Proposed Labeling which was received that morning and to discuss Barrier's request to list the function of all 3 active ingredients as opposed to listing the function only for miconazole nitrate. The Agency did not honor this request.	NDA 21-026
9-Feb-2006	Barrier provided Revised Proposed Labeling reflecting all of FDA's requests.	NDA 21-026
14-Feb-2006	FDA initiated teleconference to discuss expiration dating for Vusion and to request minor changes to Phase 4 Commitment Acceptance.	NDA 21-026
14-Feb-2006	Barrier submitted General Correspondence agreeing to 1-year expiration dating in order to obtain approval.	NDA 21-026
15-Feb-2006	Barrier provided Draft Proposed Labeling.	NDA 21-026
15-Feb-2006	Barrier submitted Response to Phase 4 Commitment Requests, as requested in the teleconference on February 14, 2006.	NDA 21-026
16-Feb-2006	VUSION™ was Approved by the FDA.	NDA 21-026